

(Submitted via Internet on May 16, 2001.)

May 16, 2001

Comments of Environmental Defense on the Trioxanes Test Plan and Robust Summary
under the High Production Volume Chemical Initiative

Environmental Defense is a national non-profit environmental advocacy organization with approximately 300,000 members dedicated to the protection of human health and the environment by, inter alia, assuring that adequate toxicity data on widely used chemicals exist and are publicly available. Environmental Defense, together with the Environmental Protection Agency and the American Chemistry Council (formerly known as Chemical Manufacturers Association), jointly developed the framework for the High Production Volume Chemical initiative. We appreciate this opportunity to comment on this test plan and robust summary, as downloaded from <http://www.epa.gov/chemrtk/viewsrch.htm>.

The Trioxane Manufacturers Consortium is not proposing any additional testing. We agree that no additional testing is necessary in the context of the HPV program.

We wish to note, however, that this conclusion is somewhat tentative with respect to reproductive toxicity. The Consortium asserts that no further reproductive testing is necessary although standard tests have not been conducted. Some reproductive data are available: ovarian function as assessed by estrous cycle duration and dominant lethal studies in males were negative, and there were no red flags for reproductive effects in repeated dose studies which analyzed histological data. However, some effects were seen at high doses in females.

While the latter finding could suggest the need for a traditional reproductive study, the question is a close one. On the whole, and given the focus of the HPV program on providing screening-level rather than definitive toxicity information, we support the decision of the Consortium to conduct no additional testing as part of the HPV program. Based on the available information, Trioxane would be considered moderate to low priority for reproductive studies by the NTP.

Thank you for this opportunity to comment.

Karen Florini, Senior Attorney
Environmental Defense
(202) 387-3500 x 118
kflorini@environmentaldefense.org

George Lucier, Ph.D.
Consulting Toxicologist